

REMARKS

I. Status Of The Claims

Claims 1-13, 16-17, 19, 22, 25 and 28 are pending. Claims 14, 15, 18, 20-21, 23-24, 26-27 and 29-81 were previously canceled without prejudice or disclaimer. *See* Form PTO-1390, Transmittal of New Application, mailed January 3, 2001. In the response, the Examiner also included these withdrawn claims in the inventive groups. *See* Office action, pages 1-2. Inasmuch as the claims provisionally elected herein differ from the claims set forth in the Office action, Applicants provisionally elected claims are proposed as claim groupings.

II. The Restriction Requirement And Applicant's Provisional Election

The Examiner required restriction, under 35 U.S.C. §§ 121, 372, between Groups 1 to 191 as these inventions or groups of inventions allegedly are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In response, Applicants hereby elect, **with traverse**, Group 11, claims 3-7, 9 and 11-12, drawn to an isolated polynucleotide encoding SEQ ID NO: 12, a host cell to encode same, and a method for producing polypeptides from said host cell.

Applicants note that the non-elected method claims should be rejoined, as a matter of right, upon allowance of a product claim. *See* MPEP § 821.04.

III. The Polypeptides Of Group 2 And The Polynucleotides Of Group 11 Exhibit Corresponding Special Technical Features

Applicants traverse the restriction requirement because the unity of invention standard must be applied in national stage applications. Section 1850 of the Manual of Patent Examining Procedure (original 8th edition, published August, 2001) (hereinafter "MPEP") provides that

when the Office considers international applications . . . during the national stage as a Designated or Elected Office under 35 U.S.C. 371, PCT Rule 13.1 and 13.2 will be followed when

considering unity of invention of claims of different categories
without regard to the practice in national applications filed
under 35 U.S.C. 111

. . .

In applying PCT Rule 13.2 to . . . national stage applications
under 35 U.S.C. 371, examiners should consider for unity of
invention all the claims to different categories of invention in
the application and permit retention in the same application for
searching and/or preliminary examination, claims to the
categories which meet the requirements of PCT Rule 13.2

MPEP at page 1800-60 to -61.

MPEP section 1893.03(d) reiterates the Examiner's obligation to apply the Unity of
Invention standard PCT Rule 13.2 instead of U.S. restriction/election of species practice:

Examiners are reminded that unity of invention (not restriction)
practice is applicable . . . in national stage (filed under 35
U.S.C. 371) applications.

Id. at page 1800-149, col. 1.

Indeed, according to Example 17, Part 2 of Annex B to the PCT Administrative
Instructions, the Examiner is obliged to find that "the protein and the DNA sequence exhibit
corresponding special technical features" and that, therefore, there is no lack of unity between
claims directed to a protein "X" and the DNA sequence that encodes protein "X."

Thus, in the present case, unity of invention does exist at least as between claims 1-2
and 16-17 of Group 2, drawn to an isolated polypeptide and a composition containing a
polypeptide that corresponds to SEQ ID NO: 2, and claims 3-7, 9 and 11-12, drawn to an
isolated polynucleotide encoding those polypeptides. Therefore, Applicants respectfully
request that the Examiner withdraw the Restriction Requirement at least as to claims 1-7, 9,
11-12 and 16-17 of Groups 2 and 11, and examine those claims in a single application.

IV. In Accordance With Office Practice, The Examination Of Claims To Nine Polynucleotide Sequences Does Not Create An Undue Burden

Applicants draw the Examiner's attention to Sections 803.04 and 1850 of the Manual of Patent Examining Procedure. While contending that nucleotide sequences that encode different proteins "constitute independent and distinct inventions" the Commissioner has decided to "permit a reasonable number of such nucleotide sequences to be claimed in a single application" so as to "further aid the biotechnology industry in protecting its intellectual property." *See id.* To this end, the Patent Office "determined that normally ten sequences constitute a reasonable number for examination purposes" and that that number does not create "an undue burden on the Office." *Id.* Indeed, the Office states that "up to ten independent and distinct nucleotide sequences will be examined in a single application without restriction." *Id.* Accordingly, the Examiner's contention that Groups 10 to 18 are "distinct from the other" and, therefore, subject to restriction, is not consistent with Office practice.

Indeed, under the "Examples of Nucleotide Sequence Claims" subsection of Section 803.04, the Office states that "[O]nly the *ten* nucleotide sequence selected in response to the restriction requirement and any other claimed sequences which are patentably indistinct therefrom *will* be examined" (emphasis added).

For this reason, Applicants further traverse the restriction requirement. Applicants contend that Groups 10 and 12-18 (claims 3-7, 9 and 11-12), drawn to an isolated polynucleotide encoding SEQ ID NO: 11, 13 and 15-20, should be examined alongside the polynucleotides of Group 11. Accordingly, Applicants kindly request that the Examiner rejoin these inventive groups and examine together these ten polynucleotides.

V. The Search Of Groups 2 and 11 Is Not Unduly Burdensome

Applicants also traverse the restriction requirement on the grounds that the search and examination of at least Groups 2 and 11 is not unduly burdensome. According to MPEP section 803 "if a search and examination of an entire application can be made without serious burden, the Examiner must examine it on the merits, even though it includes claims to

independent and distinct inventions.” As the polynucleotides of Group 11 encode the polypeptides of Groups 2, Applicants suggest examination of at least Groups 2 and 11 can be made without serious burden.

VI. Conclusion

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

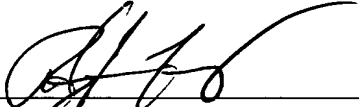
If there are any fees due in connection with the filing of this response, please charge the fees to Deposit Account No. 19-0741. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should be charged to our Deposit Account.

Respectfully submitted,

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